201-15328

rdenison@environmentaldefense.org

06/05/2004 12:51 PM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, mark_Thomson@cromptoncorp.com, NCIC HPV@EPA

cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on 3,9-Bis(2,4-di-tert-butylphenoxy)-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5,5]undecane (CAS# 26741-53-7)

(Submitted via Internet 6/5/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and mark_Thomson@cromptoncorp.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 3,9-Bis(2,4-di-tert-butylphenoxy) -2,4,8,10-tetraoxa-3,9-diphosphaspiro[5,5]undecane (CAS# 26741-53-7).

The test plan and robust summaries for this substance, known as Ultranox 626, were submitted by Crompton Corporation. The test plan states that Ultranox 626 is used as an antioxidant for polyolefins, polyesters, styrenics, engineering thermoplastics, PVC, elastomers and adhesives. No information is provided on whether or not there are releases into the environment when Ultranox 626 is used in various applications. Likewise, no data are provided on the potential for human exposures in the workplace, for environmental exposures or for exposures arising from consumer use and practices. Although not explicitly required by the HPV Program, use and exposure data are important to public and environmental health considerations.

The sponsor claims that existing data are sufficient to address SIDS endpoints, with the one exception that new water hydrolysis studies are proposed. We agree with this proposal, but we also recommend that the sponsor conduct ecotoxicity studies, and we find that the justification provided not to conduct reproductive toxicity studies is inadequate.

In regard to the ecotoxicity studies, the sponsor has applied ECOSAR estimates for all endpoints, and has concluded that the limits of solubility of this substance preclude the conduct of any meaningful studies. However, Ultranox is not biodegradable and it is a complex molecule with many functional groups. ECOSAR has wrongly predicted on many occasions in the past and since Ultranox 626 is not biodegradable, we recommend that experimental data be obtained for the three ecotoxicity endpoints.

The sponsor asserts that reproductive toxicity studies are not needed because repeat dose studies did not indicate any damage to either the male or female reproductive tract. In particular, the sponsor refers to a two-year oral feed study in rats, but there is no indication in the robust summaries that histological analyses were conducted in interim sacrifices. Two-year old rats are not a good model for detecting reproductive tract alterations because of reproductive tract senescence. Also, the only dose information provided in the repeat dose studies in rodents is the concentration of Ultranox 626 in feed. What is 500 ppm in the diet equivalent to in mg/kg/day? Based on the limited information provided in the robust summaries, we recommend that the sponsor conduct a reproductive

toxicity study using doses appropriate for such studies.

Other comments are as follows:

1. There is a reference list attached to the robust summaries, but the studies reported in the robust summaries often do not refer to this list, so it is impossible to determine the author of individual studies. This is important and needs to be remedied, because there are frequent statements that the author considered a particular finding not substance-related.

2. Ultranox 626 possesses a low order of acute toxicity, but it is does cause chromosomal aberrations in at least one assay and the repeat dose studies report a wide array of toxic effects, including liver toxicity, splenic toxicity, the presence of degenerative myelin lesions in treated dogs and eosinophilic pneumonia.

3. The sponsor estimates a NOEL of 300 ppm in the diet for splenic toxicity. However, data presented in the robust summaries indicate that there are effects in the 100 ppm group, so the NOEL is actually < 100 ppm.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense